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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,036	11/20/2000	Hortense W. Dodo	027[illegible]-0104	6841

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EXAMINER
TIBBS, TERRA C

[illegible]	PAPER NUMBER

DATE MAILED: 08/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/715,036	DODO ET AL.	
	Examiner	Art Unit	
	Terra Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-21 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to a method for producing a transgenic peanut plant with reduced or undetectable allergen protein content in the seed, comprising the steps of transforming a recipient peanut plant cell with a DNA construct comprising a peanut allergen antisense gene, or a peanut allergen sense gene, or a combination thereof, or fragments thereof; regenerating a peanut plant from the recipient cell which has been transformed with the DNA construct; and identifying a fertile transgenic peanut that produces seeds having reduced or undetectable allergen protein content, classified in class 800, subclass 278.

II. Claims 10-16 and 18, drawn to antisense, classified in class 536, subclass 24.5.

III. Claim 19 drawn to an Ara h2 promoter, classified in class 536, subclass 24.1.

IV. Claim 20 drawn to an isolated polynucleotide classified in class 536, subclass 23.1.

V. Claim 21 drawn to a method for producing a transgenic peanut plant with reduced or undetectable allergen protein content in the seed, comprising the steps of identifying a homologous region common to more than one Ara h allergen gene; cloning the homologous region in a vector modified for peanut transformation, wherein the homologous region is operably linked to a promoter; transforming a

recipient peanut plant cell with the vector; and identifying a regenerated fertile transgenic peanut plant that produces seeds having reduced or undetectable allergen protein content, classified in class 800, subclass 295.

The inventions are distinct, each from the other because of the following reasons: Inventions of Groups I-V are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to a method for producing a transgenic peanut plant with reduced or undetectable allergen protein content in the seed, comprising transforming a recipient peanut plant cell with a DNA construct; an antisense gene; an Ara h2 promoter gene; isolated polynucleotides; and a method for producing a transgenic peanut plant with reduced or undetectable allergen protein content in the seed, comprising identifying a homologous region common to more than one Ara h allergen gene, such that each different invention would require a separate classification search (e.g. an antisense is not a promoter and would not be used in a method of making a transgenic plant; a promoter cannot function as an antisense).

Inventions of Groups I and V and inventions of Groups II, III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antisense oligonucleotides complementary to Ara h1, Ara h2, Ara h3, Ara h4, Ara h5, Ara 6 and Ara h7 genes of Group II can be used as a method for producing a transgenic peanut plant with reduced

or undetectable allergen protein content in the seed, comprising transforming a recipient peanut plant cell with a DNA construct comprising a peanut plant allergen antisense gene.

The MPEP, in part, states: Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.* MPEP 803.04. It has been determined that **one** sequence constitutes a reasonable number for examination purposes (see below). Therefore, searching all of SEQ ID NOs: 1-8 would constitute a burdensome search on the nucleotide sequence searching resources of the Office.

These inventions are not disclosed as capable of use together and are independent and distinct because the different genes and their respective nucleotide sequences of Group IV have different molecular structures that result in different functions and effects than the antisense genes or promoter gene of Groups II and III, respectively. Furthermore, the inventions of Groups I and V each have different modes of operation, effects, or functions from the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Furthermore, because a separate search would be required for each one of the different genes and their respective nucleotide sequences, restriction for examination purposes as indicated is proper.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences of Groups I, II and IV are further restricted to **one** sequence. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application (see MPEP 803.04 and 2434).

Group I, drawn to a peanut allergen antisense gene, sense gene, a combination thereof, fragments thereof of SEQ ID NOS: 3, 4, 5, and 6 are further limited to **one** gene. Group II, drawn to antisense of SEQ ID NOS: 3, 4, 5, and 6 are further limited to **one** sequence. Group IV, drawn to an isolated polynucleotide of SEQ ID NO: 3, 4, 5 and 6 is further limited to **one** sequence. The sequences claimed each target and modulate expression of different Ara h genes and are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence has a unique nucleotide sequence, each sequence targets a different and specific region of its respective Ara h gene. Furthermore, each antisense, upon binding to Ara h, functionally modulates the expression of that particular gene. Therefore, a search of more than one (1) of the sequences claimed in Groups I, II and IV presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense sequences. In view of the foregoing, one **(1)** sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one **(1)** sequence from Groups I, II and IV.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Response to Amendment

Applicant's Amendment filed on 5/18/01 on page 4 is acknowledged. However, the amendment has not been properly entered. The Amendment recites, "In the Specification:

Page 9, line 22, before "shows" insert - - (SEQ ID NO:3) - -;
Page 9, line 27, before "shows" insert - - (SEQ ID NO:4) - -;
Page 10, line 2 after "shows" insert - - (SEQ ID NO:5) - -;
Page 10, line 8 after "shows" insert - - (SEQ ID NO:6) - -;
Page 10, line 13 after "shows" insert - - (piece of SEQ ID NO:1) - -;
Page 46, line 12, after "sequence" insert - - (SEQ ID NO: 7)
Page 48, line 20, after "probe" insert - - (SEQ ID NO:8)"

Regarding Page 9, "shows" is not found in lines 22 or 27. Regarding page 10, "shows" is not found in lines 2, 8 or 13. Regarding page 46, "sequence" is not found in line 12. Regarding page 48, "probe" is not found in line 20. Appropriate correction is required.

Nucleotide and/or Amino Acid Sequence Disclosure

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 1.821 through 1.825 for the reason(s) set forth below. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 Fed. Reg. 18230, May 1, 1990. It is noted that the application fails to comply with 37 CFR 1.821(d).

The instant application does not comply with 37 CFR 1.821(d) which states: "Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application". Applicant's amendment to the specification at pages 9, 10, 46 and 48 supplying the SEQ ID numbers for SEQ ID NOS: 1-8 is not sufficient to bring the application into compliance with the sequence rules because at page 47 of the specification, the sequence of "a 62 base pair probe" does not contain an accompanying identifier. Additionally, page 45 of the specification recites: "The probe sequence", but does not contain an accompanying identifier.

Applicants disclose nucleotide sequences in Figures 2-5, 7 and 9 that must be identified by a SEQ ID number, pursuant to 37 CFR 1.821(d). In particular, the MPEP states:

> It should be noted, though, that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings.

MPEP at section 2422.02, last paragraph.

Applicant's amendment to the specification (see Response to Amendment, above) supplying the SEQ ID numbers for the sequences of Figures 2-5, 7 and 9 is not sufficient to bring the application into compliance with the sequence rules because the amendment was not in compliance with 37 CFR 1.821(d). An amendment to the specification supplying the SEQ ID numbers for the sequence of Figures 2-5, 7 and 9 in the **Brief Description of the Drawings** and **The Claims** would appear to bring the application into compliance with the nucleotide sequence rules. Applicant is required to comply with the correction as per above as part of a complete response to this Office action.

Applicant is required to comply with the correction as per above as part of a complete response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg
August 2, 2002

SEAN McGARRY
PRIMARY EXAMINER
1635